

**REMARKS**

Reconsideration and withdrawal of the rejections of the application respectfully requested in view of the amendments, remarks and enclosures herewith, which place the application in condition for allowance.

**I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 84-118 are pending in this application.

The Examiner is thanked for removing the rejection of claims 84-118 based upon U.S. Patent No. 6,376,473 in view of Klavinskis et al. (J. Immunol. Vol. 162, No. 1, pages 254-262; January 1, 1999) et al. under 35 U.S.C. § 103 as well as obviousness-type double patenting.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

**II. THE SECTION 112 REJECTIONS ARE OVERCOME**

Claims 84-118 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. The rejection is respectfully traversed.

According to the Court of Appeals for the Federal Circuit in the case of *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988),

Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. 'The key word is undue, not experimentation.' The determination of what constitutes undue experimentation in a given case requires the application of standard of reasonableness, having due regard for the nature of the invention and the state of the art. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed ... [Citations omitted].

*Id.* at 1404.

Determining whether undue experimentation is required to practice a claimed invention turns on weighing many factors summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), for example: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples of the invention; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims.

Thus, it is respectfully submitted that for a proper Section 112, first paragraph, lack of enablement analysis, an Office Action must show that the *Wands* factors are not met. Simply, it is respectfully asserted that the lack of enablement rejection fails to provide a fact based analysis using the *Wands* factors that supports the proposition the claimed invention require undue experimentation.

The Examiner contends that in their broadest embodiments, the claims encompass a bovine DNA vaccine for BRSV, BVDV-1, BVDV-2, bPI-3 in combination with a cationic lipid that meets the structural limitations set forth in claim 84 and that the broad claims encompass thousands of different cationic lipids considering every possible lipid that meets the limitations set forth in claim 84. In response, the Examiner is reminded that the first paragraph of Section 112 does not require a specific example of everything within the scope of a broad claim. *In re Anderson*, 176 USPQ. 331, 333 (CCPA 1973). This is true even in an unpredictable art. *In re Obukowitz*, 27 U.S.P.Q. 2d 1063, 1067 (BPAI 1993).

The Examiner alleges that a reference by Serge Harpin et al. titled “Vaccination of cattle with a DNA plasmid encoding the bovine viral diarrhoea virus major glycoprotein E2” published in the Journal of General Virology 1999, Vol. 80:3137-3144, hereinafter referred to as “Harpin” clearly demonstrates that although cationic lipids may enhance the antibody response to an antigen in bovines, the cationic lipid is not effective as an adjuvant for a DNA vaccine in bovines because the cationic lipid abolishes the protective effect of the DNA vaccine. The Examiner also contends that Harpin demonstrates that the presence of neutralizing antibodies is not predictive of a protective response. In response, it is respectfully asserted that the Examiner has misapplied the teachings of Harpin to the presently claimed invention.

Accompanying this response is a true copy of a Declaration Under 37 C.F.R. § 1.132 by Michel Riviere. Accordingly to the Declaration, the cationic lipid of Harpin, DOTAP, is not the cationic lipid of claim 84. Therefore, the effects of DOTAP on the protective effect of a vaccine cannot be extrapolated to the presently claimed invention.

The Examiner alleges that it is unpredictable if the bovine DNA vaccine in combination with a cationic lipid would produce an effective and protective immune response and that additional experimentation would be required for one of skill in the art to use that claimed invention. Applicants respectfully disagree.

The Examiner is respectfully reminded that a specification need not contain any example of the invention, as the issue is whether the disclosure enables one skilled in the art to practice the invention without undue experimentation. *In re Borkowski*, 422 F.2d 904, 164 USPQ 642 (CCPA 1970). Simply, a determination that undue experimentation is necessary to practice the invention does not necessarily follow from a lack of examples in the specification. And, the Examiner is further respectfully reminded that an applicant need not describe all actual embodiments of a claimed invention.

Accompanying this response is a true copy of a Declaration Under 37 C.F.R. § 1.132 by Michel Riviere. The Declaration presents data that demonstrates that vaccination of calves with a BHV-1 DNA vaccine and a DMRIE-DOPE adjuvant results in an effective and protective immune response. As noted in the Declaration, the experiments were performed according to the teachings of the specification. Furthermore, similar results may be obtained with other bovine DNA vaccines. Accordingly, Applicant respectfully submits that the skilled artisan can make and use the claimed invention, without undue experimentation.

Therefore, there is a failure to provide a factual showing that the present application is not enabled. Absent factual evidence corresponding to the *Wands* factors above, the Section 112 rejection is improper and must be withdrawn. Consequently, reconsideration and withdrawal of the Section 112 rejection is respectfully requested.

**REQUEST FOR INTERVIEW**

If any issue remains as an impediment to allowance, a further interview with the Examiner and SPE are respectfully requested; and, the Office Action is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the remarks and amendments herewith, along with the Declaration Under 37 C.F.R. § 1.132, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,  
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